IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF INDIANA

IRISH 4 REPRODUCTIVE HEALTH *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Case No. 3:18-cv-0491-PPS-JEM

MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS'
MOTION TO DISMISS THE AMENDED COMPLAINT

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ISSUES STATEMENT

- 1) Can Plaintiffs raise Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.*, claims against the Federal Defendants, given that the APA precludes review of final agency actions when there are adequate alternative remedies, including Plaintiffs' potential remedy through an ERISA claim?
- 2) Can Plaintiffs challenge Federal Defendants' decision regarding how to exercise their enforcement discretion notwithstanding *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (concluding that an agency's decision to "refus[e] to take enforcement steps" is a decision presumptively committed to "an agency's absolute discretion")?
- 3) Do Plaintiffs have standing to challenge the Final Rules even though Notre Dame did not rely on them and they did not exist when Notre Dame changed its contraceptive coverage policies?
- 4) Should the Court void the settlement agreement between Federal Defendants and Notre Dame under *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (per curiam), even though the Supreme Court did not reach a decision on the merits in that case?
- 5) Should the Court enjoin the Final Rules under the APA's notice and comment rulemaking requirement when the Federal Defendants solicited and considered more than 110,000 public comments before promulgating the Final Rules?
- 6) Should the Court enjoin the final rule that expands the religious exemption to the contraceptive-coverage mandate for lack of a "valid justification," Am. Compl. ¶ 209, ECF No. 43, when the Religious Freedom Restoration Act (RFRA) authorizes (and indeed requires) the government to eliminate substantial government-imposed burdens on religious liberty, the mandate imposed such a burden, and the Patient Protection and

- Affordable Care Act (ACA) and RFRA give the government discretion in how to alleviate such burdens?
- 7) Should the Court enjoin the final rule that creates a moral exemption to the contraceptive-coverage mandate for lack of a "valid justification," Am. Compl. ¶ 209, when there is a long history of providing protections to conscience-based objections, particularly in the area of health care, and the ACA gives the government discretion to alleviate the burden on conscience?
- 8) Should the Court enjoin the Final Rules and the Settlement Agreement under the Establishment Clause when they do not endorse a particular religious belief, but rather free parties to act as they otherwise would in the absence of government-imposed regulations?
- 9) Should the Court enjoin the Final Rules and the Settlement Agreement under the Due Process Clause of the Fifth Amendment when the Supreme Court has held that individuals have no entitlement to the subsidization of their rights?
- 10) Should the Court enjoin the Final Rules and the Settlement Agreement under the Equal Protection principle of the Fifth Amendment when they do not, in fact, discriminate on the basis of sex and when they do not deprive Plaintiffs of a fundamental right, because there is no constitutional right to subsidized contraceptives?

INTRODUCTION

This action is the latest chapter in protracted litigation regarding the so-called contraceptive-coverage mandate. Since the adoption of the mandate pursuant to the ACA, numerous entities, including the University of Notre Dame, brought lawsuits to challenge both the mandate and the government-created accommodation intended to address the religious

objections of certain organizations to the mandate. On two separate occasions, the Supreme Court vacated lower court rulings denying Notre Dame's motion to enjoin governmental enforcement of the mandate; but those rulings did not resolve Notre Dame's legal objections to the mandate and the accommodation. Instead, the Court directed that the parties "on remand should be afforded an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage." *Zubik v. Burwell*, 136 S. Ct. 1560 (2016) (per curiam). Despite numerous rounds of rulemaking and the solicitation of public comments, however, the administering agencies—the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Agencies)—were unable to find a way to amend the accommodation to both satisfy organizations' conscience objections and ensure that women covered by the organizations' health plans receive contraceptive coverage.

In an effort to comply with the *Zubik* Court's direction, resolve the ongoing litigation, and alleviate the burden on those with religious or moral objections to providing or facilitating contraceptive coverage, the Agencies issued two interim final rules (IFRs) expanding the religious exemption to the mandate and creating a new exemption for organizations with moral objections. After reviewing all comments received on the IFRs, and making some changes in response, the Agencies promulgated two Final Rules superseding the IFRs. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA,

¹ See Univ. of Notre Dame v. Sebelius, 988 F. Supp. 2d 912 (N.D. Ind. 2013) (denying Notre Dame's motion for a preliminary injunction), aff'd, 743 F.3d 547 (7th Cir. 2014), cert. granted, vacated, and remanded sub nom Univ. of Notre Dame v. Burwell, 135 S. Ct. 1528 (2015), aff'd on remand, 786 F.3d 606 (7th Cir. 2015), cert. granted, vacated, and remanded, 136 S. Ct. 2007 (2016).

83 Fed. Reg. 57,536 (Nov. 15, 2018) (the Religious Exemption Rule); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (the Moral Exemption Rule) (collectively, the Final Rules). In addition, and consistent with the *Zubik* Court's direction that the parties work to "accommodat[e]" the competing interests at play, the Agencies also reached a settlement agreement ("Settlement Agreement") with Notre Dame and other entities in litigation with the government. Notre Dame announced changes to its health plan in February 2018 on the basis of this settlement, deciding to continue to cover some contraceptives, but not to cover certain contraceptives to which it has a religious objection.

Plaintiffs, a student association and individuals enrolled in health plans provided by

Notre Dame, challenge the Final Rules and the Settlement Agreement as unlawful under the

APA, the ACA, the Establishment Clause of the First Amendment, and the Due Process and

Equal Protection guarantees of the Fifth Amendment. Plaintiffs further allege that the Settlement

Agreement violates binding Supreme Court precedent.

These claims are without merit, and the Court should dismiss Plaintiffs' amended complaint with prejudice for several independent reasons. As a threshold matter, the Court lacks jurisdiction over Plaintiffs' claims. Plaintiffs cannot challenge the Settlement Agreement for two independent reasons. First, the APA only permits judicial review of final agency actions "for which there is no other adequate remedy in a court," 5 U.S.C. § 704. Here, if Plaintiffs' claims were meritorious, they would have other alternative avenues for relief, including the non-APA challenges to the Settlement Agreement they raise in their amended complaint and claims involving Notre Dame's health plans, which Plaintiffs must pursue as provided under the Employee Retirement Income Security Act of 1974 (ERISA). Second, decisions to refrain from

enforcement action, such as the Settlement Agreement, are presumptively committed to agency discretion as a matter of law and beyond the scope of judicial review. As to Plaintiffs' challenges to the Final Rules, Plaintiffs lack standing to challenge the religious exemption rule because Notre Dame relied on the Settlement Agreement—not the Final Rules—to make the changes that Plaintiffs find objectionable; indeed, the Final Rules did not yet exist when Notre Dame changed its contraceptive coverage policies. Plaintiffs also have no standing to challenge the moral exemption rule because Notre Dame, a religious institution, has never purported to rely on that exemption.

Turning to the merits, Plaintiffs are wrong to assert that issuance of the Final Rules was procedurally infirm. The Final Rules satisfy the APA's procedural requirements regardless of whether the IFRs were procedurally sound, because the Final Rules were issued after the Agencies requested and considered public comments, and they are in no way "tainted" by the IFRs lack of notice and comment. In any event, the Agencies' issuance of the IFRs was also procedurally proper.

Plaintiffs' substantive challenges to the Final Rules and Settlement Agreement also are without merit. The same provision of the ACA that authorized the Agencies to issue the original exemption for churches equally authorizes the expanded exemptions. *See* 42 U.S.C. § 300gg-13(a)(4); 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011); 82 Fed. Reg. 47,792, 47,806 (Oct. 13, 2017). Indeed, Plaintiffs' position, if adopted, would equally sweep away the longstanding exemption for churches and their integrated auxiliaries, exposing churches to the contraceptive-coverage mandate for the first time. In addition, RFRA independently authorized, and indeed required, issuance of the religious exemption as a means of eliminating the substantial burden on religious exercise that the Supreme Court held in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct.

2751 (2014), was imposed by the contraceptive-coverage mandate. The exemptions also are consistent with the Supreme Court's order in *Zubik* and are neither arbitrary nor capricious. As to Plaintiffs' constitutional claims, it is settled law that the government may accommodate religion without running afoul of the Establishment Clause; neither the Final Rules nor the Settlement Agreement advance religion, but instead relieve a burden on religious practice. Also, the Final Rules and Settlement Agreement do not draw sex- or religion-based distinctions in violation of equal protection principles, nor do they affirmatively deny access to contraceptives in violation of Plaintiffs' substantive or procedural due process rights.

The Court thus should dismiss this action.

BACKGROUND

I. The Affordable Care Act and the Contraceptive-Coverage Mandate

The ACA requires most group health plans and health-insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without "any cost sharing requirements." 42 U.S.C. § 300gg-13(a). The Act does not specify the types of women's preventive care that must be covered. Instead, as relevant here, the Act requires coverage, "with respect to women," of such "additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA]," a component of HHS. *Id.* § 300gg-13(a)(4).

In August 2011, HRSA adopted the recommendation of the Institute of Medicine to issue guidelines requiring coverage of, among other things, the full range of FDA-approved contraceptive methods for women, including oral contraceptives, diaphragms, injections and implants, emergency contraceptive drugs, and intrauterine devices. *See* 77 Fed. Reg. 8,725, 8,725-26 (Feb. 15, 2012). Coverage for such contraceptive methods was thus required for plan years beginning on or after August 1, 2012. *See* 76 Fed. Reg. at 46,623.

At the same time, the Agencies, invoking their authority under 42 U.S.C. § 300gg-13(a)(4), promulgated interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate. See 76 Fed. Reg. at 46,623; 77 Fed. Reg. at 8,725. Various religious groups urged the Agencies to expand the exemption to all organizations with religious or moral objections to providing contraceptive coverage. See 78 Fed. Reg. 8,456, 8,459-60 (Feb. 6, 2013). Instead, in a subsequent rulemaking, the Agencies offered an "accommodation" for religious not-for-profit organizations with religious objections to providing contraceptive coverage. See 78 Fed. Reg. 39,870, 39,874-82 (July 2, 2013). The accommodation allowed a group health plan established or maintained by an eligible objecting employer, or arranged for students by an eligible organization that is an institution of higher education, to opt out of any requirement to directly "contract, arrange, pay, or refer for [contraceptive] coverage," id. at 39,874, by providing notice of its objection. The regulations then generally required the employer's or school's health insurer (in the case of insured group health plans) or third-party administrator (in the case of self-insured plans) to provide or arrange payments for contraceptives for plan participants. See id. at 39,875-80.

In the case of self-insured church plans, however, coverage by the plan's third-party administrator under the accommodation was voluntary. Church plans are exempt from ERISA, and the authority to enforce a third-party administrator's obligation to provide separate contraceptive coverage derives solely from ERISA. The Agencies thus could not require the third-party administrators of church plans—and, by extension, many nonprofit religious organizations participating in those plans—to provide or arrange for such coverage or to impose fines or penalties for failing to provide such coverage. *See* 79 Fed. Reg. 51,092, 51,095 n.8 (Aug. 27, 2014).

Even apart from the exception for churches and their integrated auxiliaries, the contraceptive-coverage mandate did not apply to many employers. The ACA itself exempts from the preventive-services requirement, and therefore from any contraceptive-coverage mandate imposed as part of that requirement, so-called "grandfathered" health plans (generally, those

plans that have not made specified changes since the Act's enactment), see 42 U.S.C. § 18011, which cover tens of millions of people, see 83 Fed. Reg. at 57,541 (estimating over 25 million individuals enrolled in such plans). And employers with fewer than fifty employees are not subject to the tax imposed on employers that fail to offer health coverage, see 26 U.S.C. § 4980H(c)(2), although such small employers that do provide non-grandfathered coverage must comply with the preventive-services requirement.

II. Challenges to the Contraceptive-Coverage Mandate and Accommodation

Many employers objected to the contraceptive-coverage mandate. In *Hobby Lobby*, the Supreme Court held that RFRA prohibited applying the mandate to closely held for-profit companies with religious objections to providing contraceptive coverage. The Court held that the mandate "impose[d] a substantial burden on the exercise of religion" for such employers with religious objections, 134 S. Ct. at 2779, and that, even assuming a compelling governmental interest, application of the mandate to such employers was not the least restrictive means of furthering that interest, *id.* at 2780. The Court observed that, at a minimum, the less-restrictive accommodation made available to not-for-profit employers by the Agencies could be extended to closely held for-profit companies with religious objections. *Id.* at 2782. The Court did not decide, however, "whether an approach of this type complies with RFRA for purposes of all religious claims." *Id.*

In response to *Hobby Lobby*, the Agencies promulgated rules extending the accommodation to closely held for-profit entities with religious objections to providing contraceptive coverage. *See* 80 Fed. Reg. 41,318, 41,323-28 (July 14, 2015). But numerous entities continued to challenge the mandate. They argued that the accommodation burdened their exercise of religion because they sincerely believed that the required notice and the provision of contraceptive coverage in connection with their health plans made them complicit in providing such coverage, in contravention of their faith.

A split developed in the circuits, *see* 82 Fed. Reg. at 47,798, and the Supreme Court granted certiorari in several of the cases. Following refinement of the parties' positions suggesting a possible compromise, however, the Court vacated the judgments and remanded the cases to the respective courts of appeals. *See Zubik*, 136 S. Ct. 1557 (2016) (per curiam). The Court "d[id] not decide whether [the plaintiffs'] religious exercise ha[d] been substantially burdened, whether the Government ha[d] a compelling interest, or whether the current regulations [we]re the least restrictive means of serving that interest." *Id.* at 1560. Instead, the Court directed the Courts of Appeals to afford the parties an opportunity to resolve the dispute on remand. In the meantime, the Court precluded the government from "impos[ing] taxes or penalties on [the plaintiffs] for failure to provide the [notice required under the accommodation]." *Id.* at 1561. Similar orders were entered in other pending cases. *See e.g.*, *Notre Dame v. Burwell*, 136 S. Ct. 2007 (2016).

In response to the *Zubik* order, the Agencies sought public comment to determine whether further modifications to the accommodation could resolve the religious objections asserted by various organizations while providing a mechanism for coverage for their employees. *See* 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies received over 54,000 comments, but they could not find a way to amend the accommodation to both account for employers' religious obligations and provide contraceptive coverage to their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017).² The pending litigation—more than three dozen cases brought by more than 100 separate plaintiffs—thus remained unresolved.

In addition, some nonreligious organizations with moral objections to providing contraceptive coverage filed suits challenging the mandate. That litigation also led to conflicting decisions by the courts. *See* 82 Fed. Reg. 47,838, 47,843 (Oct. 13, 2017).

² Available at https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

III. The Interim Final Rules

In an effort "to resolve the pending litigation and prevent future litigation from similar plaintiffs," the Agencies concluded that it was "appropriate to reexamine" the mandate's exemption and accommodation. 82 Fed. Reg. at 47,799. Following that reexamination, in October 2017, the Agencies issued two IFRs that requested public comments and that expanded the exemption while continuing to offer the existing accommodation as an optional alternative. The first rule expanded the religious exemption to all nongovernmental plan sponsors, as well as institutions of higher education in their arrangement of student health plans, to the extent that those entities have sincere religious objections to providing contraceptive coverage. *See id.* at 47,806.

The Agencies acknowledged that contraceptive coverage is "an important and highly sensitive issue, implicating many different views." *Id.* at 47,799. But "[a]fter reconsidering the interests served by the [m]andate," the "objections raised," and "the applicable Federal law," the Agencies "determined that an expanded exemption, rather than the existing accommodation, [wa]s the most appropriate administrative response to the religious objections raised by certain entities and organizations." *Id.* The Agencies explained that the new approach was necessary because "[d]espite multiple rounds of rulemaking," and even more litigation, they "ha[d] not assuaged the sincere religious objections to contraceptive coverage of numerous organizations" or resolved the pending legal challenges that had divided the courts. *Id.*

The second rule created a similar exemption for entities with sincerely held moral objections to providing contraceptive coverage; unlike the religious exemption, this rule did not apply to publicly traded companies. *See* 82 Fed. Reg. 47,838. This rule was issued "in part to bring the [m]andate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues," *id.* at 47,844, as well as similar efforts by states, *id.* at 47,847, and to attempt to resolve legal challenges by moral objectors that had given rise to conflicting court decisions, *id.* at 47,843.

Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, the Agencies' use of interim final rules on three prior occasions with respect to the preventive service requirements, and the APA's general "good cause" exception, 5 U.S.C. § 553(b), the Agencies issued the IFRs without prior notice and comment. The Agencies also solicited public comments for 60 days post-promulgation in anticipation of final rulemaking. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.³

IV. Settlement of Notre Dame Case

Notre Dame sponsors health insurance plans for both students and faculty and staff (and their dependents). *See* Am. Compl. ¶ 19. In 2013, it filed a lawsuit challenging the contraceptive-coverage mandate, as modified by the accommodation. *See Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 612 (7th Cir. 2015), *cert. granted, judgment vacated*, 136 S. Ct. 2007 (2016). It argued that the accommodation made it a "conduit" for the provision of contraceptive coverage, in violation of its religious beliefs. *Id.* at 612. The Seventh Circuit rejected this argument, *id.* at 612-19, but the Supreme Court granted certiorari, vacated the Court of Appeals' decision, and remanded the case in light of the *Zubik* decision, thereby offering the parties a chance to try to resolve their dispute, *Notre Dame*, 136 S. Ct. at 2007.

Following the Supreme Court's remands, the President issued Executive Orders establishing that it is the policy of the Government "to vigorously enforce Federal law's robust protections for religious freedom" and to "exercise all authority and discretion available . . . to waive, defer, grant exemptions from, or delay the implementation of any provision or

³ The IFRs were challenged in several lawsuits and enjoined by two district courts. *See California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 814 (N.D. Cal. 2017), *aff'd in part, vacated in part, remanded sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 563 (E.D. Pa. 2017), *appeal filed, Pennsylvania v. Trump*, Nos. 17-3752 and 18-1253 (3d Cir.).

requirement of the [ACA] that would impose . . . a cost, fee, tax, penalty, or regulatory burden on . . . health insurers . . . [or] purchasers of health insurance." Exec. Order 13,798, Promoting Free Speech and Religious Liberty, 82 Fed. Reg. 21,675 (May 4, 2017); Exec. Order 13,765, Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 Fed. Reg. 8,351 (Jan. 20, 2017). The Agencies subsequently issued the IFRs discussed above, in which they stated that "requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA"; that "the application of the Mandate to certain objecting employers [i]s [not] necessary to serve a compelling governmental interest"; and that "alternative approaches can further the interest the Departments previously identified behind the Mandate." 82 Fed. Reg. at 47,800, 47,806.

In light of the remand orders, the Executive Orders, and the IFRs, the Department of Justice (DOJ) exercised its discretion to settle then-pending lawsuits, including the one brought by Notre Dame. These suits challenged the old legal regime, which was at odds with the new legal framework for contraceptive coverage foreshadowed by the Executive Orders and established in the IFRs. *See* Settlement Agreement, Compl., Ex. A, at 2-3, ECF No. 1-1 (noting, in justifying the settlement, that the remand, Executive Orders, and new rules have placed the litigation in an "extraordinary posture"). The Settlement Agreement with Notre Dame executed on October 13, 2017 provides, in relevant part, that "[t]he Government [] will treat Plaintiffs and their health plans, including their insurance issuers and/or third party administrators in connection with those health plans, as exempt from the Regulations [in place prior to the IFRs] or any materially similar regulation or agency policy." *Id.* at 4, ¶ 2. The agreement goes on to define a "materially similar regulation or agency policy" as one that "includes any requirement

that Plaintiffs, their insurance issuers, or their third-party administrators provide any of the Objectionable Coverage through or in connection with Plaintiffs' health plans." *Id.*

V. The Final Rules

The Agencies requested public comment on the IFRs. After considering, for over 11 months, the more than 110,000 comments received on the IFRs, on November 15, 2018, the Agencies issued final versions of the religious exemption and the moral exemption rules. Throughout the preamble, the Final Rules address the significant comments received by the Agencies. The Agencies made changes in response to the comments, but those changes do not alter the fundamental substance of the exemptions set forth in the IFRs.

The religious exemption, in its final form, as in its interim final form, is "necessary to expand the protections for the sincerely held religious objections of certain entities and individuals." 83 Fed. Reg. at 57,537. It "minimize[s] the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing." *Id.* The final religious exemption "do[es] not remove the contraceptive coverage requirement generally from HRSA's Guidelines." *Id.* What it does do is "finalize exemptions [for] the same types of organizations and individuals for which exemptions were provided in the Religious [IFR]: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals." *Id.* "In addition, the [religious exemption rule] maintain[s] a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators." *Id.*

In response to comments on the religious IFR, the Agencies made a number of clarifying or technical changes in the final rule. For example, "[t]he prefatory language to the exemptions

is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections." *Id.*; *see also id.* (listing modifications). Also, the Agencies "revise[d] the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement." *Id.*

The final moral exemption rule also continues to fulfill the same purpose that it did in its interim form, namely, to "protect sincerely held moral objections of certain entities and individuals." 83 Fed. Reg. at 57,592. The Agencies considered public comments asking for the moral exemption to be expanded to publicly traded or government entities, but declined to do so. *Id.* at 57,616-19. Importantly, like the religious exemption rule, the moral exemption rule "do[es] not remove the contraceptive coverage requirement generally from HRSA's guidelines." *Id.* at 57,593. And "[t]he changes to the rule[] being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage." *Id.*

The Final Rules were set to go into effect on January 14, 2019, but have been preliminarily enjoined by two district courts. *See California v. Health and Human Servs.*, 4:17-cv-5783, 2019 WL 178555 (N.D. Cal. Jan. 13, 2019) (issuing preliminary injunction against implementation of Final Rules in fourteen plaintiff-states); *Commonwealth of Pennsylvania v. Trump*, 2:17-cv-4540, 2019 WL 190324 (E.D. Pa. Jan. 14, 2019) (entering nationwide preliminary injunction). The Agencies have appealed both decisions. *See California v. Health and Human Servs.*, No. 19-15118 (9th Cir. Jan. 24, 2019); *Commonwealth of Pennsylvania v. President of the United States*, No. 19-1189 (3d Cir. Jan. 24, 2019).

VI. The Present Case

In February 2018, after execution of the Settlement Agreement but before issuance of the Final Rules, Notre Dame announced that its health plans would not cover contraceptive methods that it views as abortifacients or sterilization (which had never been covered) because of the University's "grave[]" religious objections to such methods; but the University would cover other contraceptive methods. *See* Letter from Rev. John Jenkins, President of the Univ. of Notre Dame, to Faculty and Staff (Notre Dame President's Letter), (Feb. 7, 2018), https://president.nd.edu/writings-addresses/2018-writings/letter-on-health-care-coverage/;⁴ Am. Compl. ¶ 130. Plaintiffs assert in their amended complaint that, for the contraceptives that are covered by Notre Dame, plan participants must pay co-pays or deductibles. Am. Compl. ¶ 8, 147-79.

In June 2018, Plaintiffs—a student association and individuals who use Notre Dame's faculty or student health plans—filed this lawsuit against the Agencies, their Secretaries (in their official capacities), and the University. Am. Compl. ¶¶ 13-19. Defendants moved to dismiss. Before the parties completed briefing, the Agencies issued the Final Rules. Plaintiffs' subsequently amended their complaint. The amended complaint includes seven causes of action directed at Federal Defendants: (1) the Settlement Agreement violates the APA, Am. Compl. ¶¶ 165-82; (2) the Settlement Agreement is void under federal common law because it is illegal under the *Zubik* remand order, the ACA, and the Constitution, Am. Compl. ¶¶ 183-88; (3) the Final Rules violate the APA because *the IFRs* were issued without pre-promulgation notice-and-comment, despite the subsequent notice-and-comment prior to the promulgation of the Final

⁴ The letter is incorporated in the Amended Complaint by reference, so it may be considered without converting this motion to a motion for summary judgment. *Hecker v. Deere & Co.*, 556 F.3d 575, 582 (7th Cir. 2009) (noting that the Seventh Circuit has been "relatively liberal" in considering documents without converting motions to dismiss into motions for summary judgment).

Rules, Am. Compl. ¶¶ 189-98; (4) the Final Rules violates the APA, because they contradict the Constitution and the ACA, Am. Compl. ¶¶ 199-212; (5) the Settlement Agreement and the Final Rules violate the Establishment Clause, Am. Compl. ¶¶ 213-17; (6) the Settlement Agreement and the Final Rules violate the Due Process Clause, by depriving plaintiffs of a fundamental right (access to contraceptives) without notice and an opportunity to be heard, Am. Compl. ¶¶ 218-24; and (7) the Settlement Agreement and Final Rules violate the Equal Protection Clause because, among other alleged reasons, they "target women for adverse treatment," Am. Compl. ¶¶ 225-232.

ARGUMENT

I. The Court Should Dismiss Many of Plaintiffs' Claims for Threshold Reasons.

A. Plaintiffs' APA Challenges to the Settlement Agreement (Count I) May Not Proceed.

In Count I, Plaintiffs allege that the Settlement Agreement between the Agencies and Notre Dame violates the APA for numerous reasons. *See* Am. Compl. ¶¶ 165-82. The Court should not reach these challenges for two independent reasons. First, the availability of adequate alternative remedies for Plaintiffs' alleged injuries bars Plaintiffs' APA challenges to the Settlement Agreement. Second, even if there were no alternative remedies, the APA challenges are unreviewable under 5 U.S.C. § 701(a)(2), because the Agencies' decision to settle litigation is an exercise of enforcement discretion that is committed to agency discretion.⁵

1. Alternative Remedies Exist.

The APA only permits a plaintiff to obtain judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704; U.S. Army Corps of Eng'rs

⁵ Plaintiffs' non-APA challenges to the Settlement Agreement (Counts II, V-VII) fail to state a claim, as discussed *infra* at Part II.A, Part II.C, and Part II.D.

v. Hawkes Co., 136 S. Ct. 1807, 1815 (2016). An alternative remedy is adequate if it would remedy the injury about which the plaintiff complains. See Coker v. Sullivan, 902 F.2d 84, 90 n.5 (D.C. Cir. 1990). Here, numerous such remedies exist.

Indeed, Plaintiffs already are pursuing alternative remedies that would cure the injuries about which they complain, were their claims meritorious. For example, Plaintiffs argue in their non-APA claims in this case that the Settlement Agreement will cause them to "lose meaningful access to contraceptive services," Am. Compl. ¶ 1, and that the Settlement Agreement should be enjoined because they believe it to be "illegal under and contrary to controlling orders and precedential decisions of the federal courts, federal statutes, and the U.S. Constitution." Am. Compl. ¶ 166. If Plaintiffs were to prevail on any of these non-APA challenges to the Settlement Agreement and it were voided, then the Settlement Agreement could not cause Plaintiffs to "lose meaningful access to contraceptive services."

Moreover, Plaintiffs Natasha Reifenberg, Jane Doe 2, and Jane Doe 3—who are all enrolled as dependents in Notre Dame's faculty and staff health plan, Am. Compl. ¶¶ 14, 16, 17—have an additional adequate alternative remedy. As ERISA plan beneficiaries, they may bring a civil action to enjoin any act or practice that they believe violates any provision of title I of ERISA or the terms of the plan. 29 U.S.C. § 1132(a)(3). Because the relevant ACA provisions requiring coverage of preventive services were incorporated into title I of ERISA, these plaintiffs would have a cause of action if they believed their plan did not conform to the contraceptive-coverage mandate. *See id.*; 29 U.S.C. § 1104(a)(1)(D); *see also* 29 U.S.C. § 1132(a)(1)(B). If Plaintiffs were successful, this Court would have the power to provide "appropriate equitable relief" to remedy injuries flowing from any violation of title I of ERISA or the terms of the plan. 29 U.S.C. § 1132(a)(3); *see also CIGNA Corp. v. Amara*, 563 U.S. 421,

438–44 (2011) (discussing the scope of "appropriate equitable relief" under 29 U.S.C. § 1132(a)(3)). Because of these adequate alternative remedies, Plaintiffs cannot pursue their APA challenges to the Settlement Agreement.

2. The Decision to Settle Litigation Is Committed to Agency Discretion.

Plaintiffs' APA challenges to the Settlement Agreement should also be dismissed for lack of jurisdiction because the Settlement Agreement is an exercise of enforcement discretion that is "committed to agency discretion by law," 5 U.S.C. § 701(a)(2), and therefore beyond the scope of APA review. Agency action is committed to agency discretion by law when the statute is drawn so that a court would have "no meaningful standard against which to judge the agency's unfettered exercise of discretion." *Vahora v. Holder*, 626 F.3d 907, 917 (7th Cir. 2010) (internal citation omitted). In other words, there is "no law to apply." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 410 (1971), *abrogated by Califano v. Sanders*, 430 U.S. 99 (1977). The "classic example of such an action is an agency's decision not to prosecute." *Home Builders Ass'n of Greater Chi. v. U.S. Army Corps of Eng'rs*, 335 F.3d 607, 615 (7th Cir. 2003).

In *Heckler v. Chaney*, the Supreme Court held that an agency's decision to "refus[e] to take enforcement steps" is a decision presumptively committed to "an agency's absolute discretion" and "general[ly] unsuitab[le] for judicial review." 470 U.S. 821, 831 (1985). The Court gave three primary rationales. First, "an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," such as whether "agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies," and whether the agency has the resources to undertake the action at all. *Id.* Second, "when an agency refuses to act it generally does not exercise its

coercive power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id.* at 832. Finally, "an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive branch not to indict – a decision which has long been regarded as the special province of the Executive Branch, inasmuch as it is the Executive who is charged by the Constitution to 'take Care that the Laws be faithfully executed." *Id.* (internal citation omitted). In *Chaney*, the Court noted that the presumption of commitment to agency discretion can be rebutted when the substantive statute has provided guidelines for the agency to follow in exercising its discretion. *Id.* at 832-33.

Courts have extended the *Chaney* presumption to agency decisions to settle enforcement actions. *See*, *e.g.*, *N.Y. State Dep't of Law v. FCC*, 984 F.2d 1209, 1213-15 (D.C. Cir. 1993); *Mahoney v. U.S. Consumer Prods. Safety Comm'n*, 146 F. App'x 587, 589, at *2 (3d Cir. 2005); *see also United States v. Carpenter*, 526 F.3d 1237, 1241-42 (9th Cir. 2008) (concluding that the Attorney General's decision to settle civil litigation is committed to agency discretion); *Energy Transp. Grp.*, *Inc. v. Skinner*, 752 F. Supp. 1, 13 (D.D.C. 1990), *aff'd sub nom. Energy Transp. Grp.*, *Inc. v. Mar. Admin.*, 956 F.2d 1206 (D.C. Cir. 1992) ("[T]he decision to settle litigation or approve the settlement of litigation to which the United States is a party is akin to an agency's decision not to institute enforcement proceedings or a prosecutor's decision not to prosecute.").

A clear and unambiguous expression from Congress is required to limit the Attorney General's authority to conduct litigation involving the United States. *Swift & Co. v. United States*, 276

U.S. 311, 316-17 (1928); *United States v. Hercules, Inc.*, 961 F.2d 796, 798-99 (8th Cir. 1992); *see also United States v. Int'l Union of Operating Eng'rs*, 638 F.2d 1161, 1162 (9th Cir. 1979).

Applying *Chaney* to the Government's settlement decisions is appropriate. Like the decision not to initiate an enforcement action, the decision to settle is a decision to "refuse to take enforcement steps," *Chaney*, 470 U.S. at 831. What is more, the same rationales for the *Chaney* presumption apply in the settlement context. The decision to settle involves a "complicated balancing" of factors within the agencies' expertise, such as the availability of resources, policy goals, and prospects for success. *N.Y. State Dep't of Law*, 984 F.2d at 1213. The refusal to take additional enforcement steps also does not constitute an exercise of coercive power. To the contrary, it is a refusal to exercise coercive power. *Id.* And to continue the analogy to prosecutorial discretion set out in *Chaney*, just as prosecutors have the discretion to decline to indict, so too do they have the discretion to enter plea bargains, *McCleskey v. Kemp*, 481 U.S. 279, 312 (1987)—thus agencies, another component of the Executive Branch, have the discretion to settle administrative enforcement actions. In short, precedent and reason demonstrate that an agency's decision to settle is committed to its discretion and so unsuitable for judicial review.

These considerations apply with full force to the Settlement Agreement here because both procedurally and substantively, the agreement reflects a decision by the Executive over the manner by which it will exercise its enforcement discretion. As a matter of procedure, the discretion to conduct litigation is committed by statute to DOJ, under the direction of the Attorney General. 28 U.S.C. § 516; *see also* 28 U.S.C. §§ 517-19. This discretion includes the power to agree not to pursue further litigation, through settlement. *See Skinner*, 752 F. Supp. at 13. The Settlement Agreement is one such settlement, terminating ongoing litigation between the Government and Notre Dame, in the discretion of the Agencies and DOJ. By agreeing not to pursue litigation against Notre Dame to enforce the contraceptive coverage mandate with respect

to coverage to which Notre Dame objected on religious grounds, the Settlement Agreement, in substance, reflects an act or judgment of executive non-enforcement. *See* Settlement Agreement at 3-7. In particular, the Government agreed that it would not enforce any fines or penalties against Notre Dame for failing to provide the objectionable coverage. *See id.* at 5-6. For these reasons, the Government's decision to enter into a Settlement Agreement, under which it agreed not to pursue certain enforcement action, is committed to the Agencies' and DOJ's discretion and beyond the reach of APA review. Plaintiffs' APA challenges to the Settlement Agreement thus should be dismissed.

B. Plaintiffs Lack Standing to Challenge the Final Rules (Counts III-VII).

All of Plaintiffs' claims challenging the Final Rules should be dismissed for lack of standing. To establish standing, Plaintiffs must demonstrate that they have suffered an injury in fact, that is traceable to the Final Rules, and that can be redressed by an order of the Court directed at the Final Rules. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). Plaintiffs cannot satisfy this standard because an order enjoining the Final Rules will not redress Plaintiffs' alleged injuries (*i.e.*, Notre Dame's refusal to cover certain contraceptives).

Notre Dame made the decision not to cover certain contraceptives before the Final Rules were issued. And, when it announced its decision, Notre Dame explained that it was based on the Settlement Agreement: "In October 2017, however, the case was settled favorably, giving the University, its insurers and third party administrators the option of an exemption from providing these drugs and services." *See* Notre Dame President's Letter. Notre Dame's decision would therefore be unaffected by enjoining or vacating the Final Rules because the basis for its decision—the Settlement Agreement—would still exist. In other words, Plaintiffs' claimed injuries are not traceable to the Final Rules and thus Plaintiffs lack standing to challenge them.

Plaintiffs, moreover, cannot establish standing by speculating that one day Notre Dame *might* rely on the Final Rules to take an action that might harm the Plaintiffs. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (concluding that standing cannot be based on a speculative injury). The need to avoid resolving claims based on speculative injuries is especially acute when those claims are constitutional claims: "[F]ederal courts are supposed to do what they can to avoid making constitutional decisions, and strive doubly to avoid making unnecessary constitutional decisions." *ISI Int'l, Inc. v. Borden Ladner Gervais LLP*, 256 F.3d 548, 552 (7th Cir. 2001), as amended (July 2, 2001).

Furthermore, even if Notre Dame's decision to change its contraceptive coverage policies could somehow be tied to the religious exemption rule, it could not be tethered to the moral exemption rule. Notre Dame has never claimed that its objections are grounded in nonreligious moral views. Plaintiffs' alleged injuries thus are not caused by the moral exemption rule. *See*, *e.g.*, Notre Dame President's Letter.

For these reasons, all of Plaintiffs' challenges to the Final Rules should be dismissed for lack of jurisdiction.

⁶ Not only is there uncertainty about what Notre Dame will do in the future as to these issues (and it has changed course several times in this regard, Am. Compl. ¶¶ 118, 124-25, 128), but there also is no certainty that Plaintiffs will be eligible for, or will choose to participate in, Notre Dame's health plans in the future.

II. The Court Should Dismiss This Case Because the Amended Complaint Fails to State a Claim Upon Which Relief May Be Granted.⁷

A. The Settlement Agreement Is Not Void for Illegality (Count II).

In Count II, Plaintiffs allege that the Settlement Agreement is void for illegality under federal common law because it violates the ACA, the Establishment Clause, the Due Process Clause, and the Supreme Court's rulings in *Zubik v. Burwell*, 136 S. Ct. at 1557, and *Univ. of Notre Dame v. Burwell*, 136 S. Ct. at 2007. *See* Am. Compl. ¶¶ 183–88. The first three challenges fail for the reasons explained in the sections of this brief addressing the same challenges to the Final Rules. *See infra* Part II.D; *see also supra* at Part I.A (discussing Count I's APA challenge to the Settlement Agreement). The final challenge also fails. The Settlement Agreement does not violate the Supreme Court's orders in *Zubik* and *Notre Dame*, because neither mandated a particular resolution of Notre Dame's original lawsuit.

In *Zubik* and *Notre Dame*, the Supreme Court vacated and remanded the cases to the circuit courts, with an instruction that, on remand, the parties should be "afforded an opportunity to arrive at an approach going forward" that balanced the competing positions of the parties. 136 S. Ct. at 1560; 136 S. Ct. at 2007 (incorporating *Zubik*'s reasoning). In doing so, the Court provided its characterization of what an ideal resolution would look like: one that "accommodates petitioners' religious exercise while at the same time ensuring that women

⁷ Nor should this Court award Plaintiffs the nominal damages that they request, Am. Compl. at 47, Prayer for Relief (h), because they cannot identify any applicable waiver of the Government's sovereign immunity. "It is elementary that '[t]he United States, as sovereign, is immune from suit save as it consents to be sued." *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (ellipses omitted) (quoting *United States v. Sherwood*, 312 U.S. 584, 586 (1941)). The APA's waiver of sovereign immunity permits suits against federal agencies for "relief other than money damages" in specific circumstances, 5 U.S.C. § 702, but plainly does not allow recovery of monetary damages. *See Veluchamy v. FDIC*, 706 F.3d 810, 815 (7th Cir. 2013) ("As the Supreme Court has explained, the United States has not waived its sovereign immunity when it comes to APA claims seeking money damages." (citing *Dep't of Army v. Blue Fox, Inc.*, 525 U.S. 255, 260 (1999))).

covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage." But the Court did not mandate that the parties pursue one course of action over another or that the Agencies ultimately succeed in fulfilling the Court's ideal. It simply vacated and remanded the cases with an instruction that the parties should *attempt* to resolve the cases in the manner described. *See Zubik*, 136 S. Ct. at 1560–61 (courts of appeal should "allow the parties sufficient time to resolve any outstanding issues between them"); *Notre Dame*, 136 S. Ct. at 2007.

And the parties did just that. The Agencies engaged in months of negotiation with the plaintiffs in the pending cases, and they issued a request for information seeking public input. Despite the negotiations and the submission of over 54,000 public comments, however, the Agencies could not find a way to amend the accommodation to both resolve the religious objections asserted by various organizations and provide a mechanism for coverage for their employees. *See* FAQs About Affordable Care Act Implementation Part 36, at 4 (Jan. 9, 2017). Accordingly, the Government relied on its authority under the ACA and RFRA and its enforcement discretion to issue the IFRs and to execute the Settlement Agreement. The Settlement Agreement thus is fully consistent with the Supreme Court's orders.

Plaintiffs argue that the Settlement Agreement is illegal because it violates *Zubik*'s reference to "full" coverage, Am. Compl. ¶¶ 80, 111, 170–72, 186a, but the Settlement Agreement does not preclude plan participants or beneficiaries from receiving the contraceptive coverage to which Notre Dame objects on religious grounds. The Settlement Agreement simply requires that any such coverage be provided "through a separate or distinct health plan, or other arrangement that is separate and distinct from [Notre Dame's] health plan." Settlement

Agreement at 4. Although this resolution may not have been the one Plaintiffs would have chosen, it is not contrary to the Supreme Court's orders in *Zubik* or *Notre Dame*.⁸

B. The Final Rules Are Procedurally Proper (Count III).

In their original complaint, Plaintiffs claimed that the IFRs were procedurally flawed because the public did not receive "notice of and an opportunity to comment" on the IFRs. Compl. ¶ 189, ECF No. 1. In Count III of their amended complaint, Plaintiffs raise a procedural challenge to the Final Rules. Although Plaintiffs acknowledge that the Agencies solicited public comments prior to promulgating the Final Rules, see, e.g., Am. Compl. ¶ 197, they assert that any procedural deficiencies in the IFRs continue to infect the Final Rules because the rules are similar. This claim fails for two reasons. First, regardless of whether there was a defect in the procedure used to issue the IFRs, the Final Rules do not suffer from the same defect, because the Agencies solicited and considered public comments before issuing the Final Rules. Second, in any event, Plaintiffs' premise is flawed—issuance of the IFRs without notice and comment was procedurally proper.

1. The Agencies Engaged in Notice-And-Comment Prior to Promulgating the Final Rules.

Plaintiffs' procedural challenge to the Final Rules is baseless because the Agencies provided the notice and comment period required under APA § 553 with respect to the Final Rules. Section 553(b) requires that an agency provide notice, an opportunity to be heard, and publication of a final rule no less than 30 days before it is to go into effect. 5 U.S.C. § 553(b).

⁸ Count I alleges that the Settlement Agreement violates the APA, for reasons largely coextensive with Plaintiffs' separate challenge to the Settlement Agreement in Count II and with Plaintiffs' APA challenges to the Final Rules. *See* Am. Compl. ¶¶ 165-82. Count I thus fails to state a claim for the reasons discussed in the other respective sections of this brief addressing Count II and Plaintiffs' challenges to the Final Rules.

Plaintiffs had that full and timely notice and ample opportunity for comment. Indeed, the Agencies received and considered more than 110,000 public comment submissions across both Final Rules, and detailed their consideration of those submissions in the final rulemakings. *See* 83 Fed. Reg. at 57,540 (religious rules); 83 Fed. Reg. at 57,596 (moral rules). The Agencies also made numerous changes in response to those comments, *see* 83 Fed. Reg. at 57,556-73; 83 Fed. Reg. at 57,613-26 (highlighting comments, responses, and changes).

In what appears to be the only Seventh Circuit case to examine the issue, the court held that a final rule that was promulgated after notice and comment, subsequent to an interim final rule, was procedurally valid under the APA. See U.S. Steel Corp. v. EPA, 605 F.2d 283, 291 (7th Cir. 1979). In analyzing the argument that the final rule was procedurally deficient, the court stated: "we cannot say that the rule under review would have been any different if notice and comment had occurred before the effective date. It is important to realize that the rule under review here is the rule as finally promulgated . . . Given that the agency was clearly willing to consider, fully and objectively, all comments in the post-promulgation period, there is no reason to believe that its consideration of the comments would have been any different if completed before the effective date." Id. Thus, the court held that it could not "make the required finding that the rule would have been different if the notice and comment period had occurred earlier."

Id. 9 Here, Plaintiffs have failed to allege anything to show that the Final Rules would have been

⁹ Other circuits have likewise concluded that a final rule may be valid notwithstanding the invalidation of a prior interim rule for failure to provide notice and comment. *See Levesque v. Block*, 723 F.2d 175, 188 (1st Cir. 1983) (voiding an interim final rule for failure to provide notice and comment, but letting the final rule stand); *Paulsen v. Daniels*, 413 F.3d 999, 1008 (9th Cir. 2005) (invalidating an interim rule for failure to comply with notice-and comment procedures and holding that the rule in effect was the final rule, where the rule previously in force had erroneously interpreted a statutory provision); *Buschmann v. Schweiker*, 676 F.2d 352 (9th Cir. 1982) (invalidating interim rule and accepting parties' agreement that final rule was valid). In addition, courts have recognized that even where an agency improperly dispenses with notice and comment procedures, the proper remedy is to offer the lost opportunity to comment rather than enjoining the rule. *See, e.g., Sharon Steel Corp. v.* EPA, 597 F.2d 377, 381 (3d Cir. 1979); *W. Oil & Gas Ass'n v. U.S. EPA*, 633 F.2d 803, 812-13 (9th Cir. 1980). As explained above, Plaintiffs had that opportunity here.

different if the notice and comment period had occurred earlier. Their procedural claim thus fails.

Plaintiffs instead maintain that the Agencies did not keep an "open mind" when evaluating comments. *See* Am. Compl. ¶ 197. But Plaintiffs purported support for this assertion falls flat.

First, even accepting Plaintiffs' allegations as true, it would be irrelevant that the IFRs and the Final Rules were "functionally and materially the same," Am. Compl. ¶ 197a, that the Agencies had entered into settlement agreements based in part on the IFRs, see Am. Compl. ¶ 197f, or that the Agencies had solicited comments on revised forms to implement the IFRs before the comment period for the Final Rules had closed, Am. Compl. ¶ 197c. The Final Rules describe in great detail the Agencies' consideration of comments and that is all the APA requires. See 83 Fed. Reg. at 57,540; 83 Fed. Reg. at 57,596. Plaintiffs may have preferred that the Agencies radically change course from the IFR to the Final Rule, but the APA does not require such a shift. In any event, the Final Rules do, in fact, make changes to the IFRs, though not the about-face Plaintiffs desired. See 83 Fed. Reg. at 57,556-73; 83 Fed. Reg. at 57,613-26. And Plaintiffs' allegation that the Agencies accepted comments on the new EBSA Form 700 after issuance of the IFR confirms that the Agencies did maintain an open mind, not that they did not. See Am. Compl. ¶ 105c.

Nor did the preliminary injunctions against the IFRs require the Agencies to change course in the Final Rules. *See* ECF No. 60, *Pennsylvania v. Trump*, No. 17-4540 (E.D. Pa. Dec. 15, 2017); ECF No. 105, *California v. Trump*, No.17-cv-05783-HSG (N.D. Cal. Dec. 21, 2017). The Agencies appealed these *preliminary* decisions, and simply maintaining a consistent legal position as to the substance of a rule does not mean that the Agencies were not open to considering the comments they received. To the extent that Plaintiffs argue the Agencies should have addressed the concerns of the courts in *Pennsylvania* and *California*, Am. Compl. ¶ 197e, the Agencies did address these substantive concerns. *See generally* Part I, II. Finally, contrary to Plaintiffs' assertions (Am. Compl. ¶ 179d,), the Agencies did address comments regarding the

benefits and effectiveness of contraception, *see e.g.* 83 Fed. Reg. at 57,552-53. Again, Plaintiffs may not agree with how the Agencies resolved these comments, but that is not what the APA requires. Because the Agencies received and carefully considered public comments before issuing the Final Rules, Plaintiffs' notice and comment claim fails.

2. Even if Any Procedural Impropriety in the IFRs Could Infect the Final Rules, the IFRs Were Procedurally Proper.

Plaintiffs' notice and comment claim is premised on the theory that any procedural deficiencies in the IFRs continue to infect the Final Rules. As explained above, the Final Rules, which were promulgated after notice and comment, were not "tainted" by any procedural flaws in the IFRs. But even if they were, Plaintiffs' premise is also wrong—the IFRs were not procedurally flawed. The Agencies had independent statutory authority, and good cause, to issue the IFRs.

The Agencies promulgated the IFRs pursuant to the ACA's preventive-services provision, 42 U.S.C. § 300gg-13. Section 2792 of the Public Health Service Act authorizes the Secretary of HHS to promulgate "such regulations as may be necessary or appropriate to carry out the provisions of [title XXVII of the Act]," along with "any interim final rules as the Secretary determines are appropriate to carry out [title XXVII]." 42 U.S.C. § 300gg-92. Corresponding provisions in ERISA (section 734, 29 U.S.C. § 1191c) and the Internal Revenue Code (section 9833, 26 U.S.C. § 9833) likewise authorize the Secretary of Labor and the Secretary of the Treasury, respectively, to promulgate not only "such regulations as may be necessary or appropriate" but also "any interim final rules as the Secretary determines are appropriate to carry out [part 7 of subtitle B of title I of ERISA (requirements for group health plans) and chapter 100 of subtitle K of the Internal Revenue Code (requirements related to health-insurance coverage)]." Congress placed the ACA's preventive services provision in title

XXVII of the Public Health Service Act, part 7 of subtitle B of title I of ERISA, and chapter 100 of subtitle K of the Internal Revenue Code.

These provisions granted the Agencies discretion to depart from normal notice-andcomment requirements in promulgating the IFRs, as the Agencies had previously done in promulgating different iterations of the contraceptive mandate. See, e.g., 76 Fed. Reg. at 46, 621 (interim final rules authorizing HRSA to exempt churches and their integrated auxiliaries from the contraceptive-coverage mandate). While Congress must act "expressly" to authorize departure from the APA's notice-and-comment requirement, 5 U.S.C. § 559, Congress need not "employ magical passwords," Marcello v. Bonds, 349 U.S. 302, 310 (1955). Congressional intent to dispense with notice and comment thus can be gleaned from "the text, context, and relevant historical treatment of the provision at issue." Musacchio v. United States, 136 S. Ct. 709, 717 (2016) (citation omitted). Here, the statutes' references to "interim final rules" manifests Congress's clear intent to confer discretion on the Agencies to depart from the APA's notice-and-comment requirement. See Asiana Airlines v. FAA, 134 F.3d 393, 398 (D.D.C. 1998) (finding express congressional intent to allow departure from APA's notice-and-comment requirement where statute authorized "not a proposed rule, but an 'interim final rule"); Methodist Hosp. of Sacramento v. Shalala, 38 F.3d 1225, 1237 (D.C. Cir. 1994) (statute authorizing issuance of IFRs followed by opportunity for comment expressed Congress's "clear intent" that APA's notice-and-comment procedures "need not be followed").

Moreover, the Agencies had good cause to issue the IFRs. There are two relevant "good cause" standards within the APA. First, an agency may issue IFRs without engaging in notice and comment at all when the agency for good cause finds that prior notice-and-comment procedures "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C.

§ 553(b)(3)(B). Second, when an agency "only dispenses with *prior* notice and comment, and not notice and comment altogether," Section 553(d)(3) of the APA applies, which "encompass[es] more situations" than those specified by 553(b)(3)(B). *U.S. Steel Corp.*, 605 F.2d at 289-90.

In a case such as this one, "where a regulation is made effective before notice and comment, the agenc[ies] could rely on either 'good cause' provision." Id. at 286. Here, as the preamble to the religious exemption IFR explains, waiting for the completion of notice and comment procedures before making the IFRs effective was "impracticable" and "contrary to the public interest" under section 553(b)(3)(B) because the status quo was untenable. The Agencies had "been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations [we]re fully exempt [or] ha[d] permanent court orders blocking the contraceptive coverage requirement." 82 Fed. Reg. at 47,814. But still "[o]ther objecting entities," including some not-for-profit entities that sued the Agencies, did not have "the protection of court injunctions." Id. To add to the uncertainty, the courts of appeals were divided on whether the accommodation imposed a substantial burden on organizations with religious objections. See 82 Fed. Reg. at 47,798 (citing cases). Given this unsustainable state of affairs and the Agencies' determination that "requiring certain objecting entities or individuals to choose between the [m]andate, the accommodation, or penalties for noncompliance has violated RFRA," 82 Fed. Reg. at 47,814, good cause existed to bypass the normal notice-and-comment requirements.

C. The Final Rules Are Neither Contrary to Law nor Arbitrary and Capricious (Count IV).

In Count IV, Plaintiffs allege that the Final Rules violate the Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), and are arbitrary and capricious because they "were

adopted with no valid justification." Am. Compl. ¶¶ 206-07, 209. Not so. The Final Rules are consistent with the Women's Health Amendment. Moreover, the Agencies adequately explained that the Final Rules' exemptions eliminate the substantial burden on religious exercise imposed by the contraceptive-coverage mandate and protect objections of conscience in the area of sensitive health-care issues.

1. The Final Rules Are Not Contrary to the Women's Health Amendment.

The ACA grants HRSA, and in turn the Agencies, significant discretion to shape the content and scope of any preventive-services guidelines adopted pursuant to § 300gg-13(a)(4). The ACA does not specify the types of preventive services that must be included in such guidelines. Instead, as relevant here, it provides only that, "with respect to women," coverage must include "such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a)(4). Several textual features of § 300gg-13(a) demonstrate that this provision grants HRSA broad discretionary authority.

First, unlike the other paragraphs of the statute, which require preventive-services coverage based on, *inter alia*, "current recommendations of the United States Preventive Services Task Force," recommendations "in effect . . . from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention," or "the comprehensive guidelines" that HRSA had already issued with respect to preventive care for children, the paragraph concerning preventive care for women refers to "comprehensive guidelines" that did not exist at the time. *Compare* 42 U.S.C. § 300gg-13(a)(1), (2), (3), *with id.* § 300gg-13(a)(4). That paragraph thus necessarily delegated the creation of the guidelines to HRSA.

Second, nothing in the statute mandated that the guidelines include contraception, let alone for all types of employers with covered plans. On the contrary, the statute provides only for coverage of preventive services "as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). The use of the phrase "for purposes of this paragraph" makes clear that HRSA should consider the particular context in shaping the guidelines, and the use of the phrase "as provided for"—absent in parallel statutory provisions—suggests that HRSA has discretion to define not only the services to be covered under that directive, but also the manner or reach of that coverage. *See also* 83 Fed. Reg. at 57,540 n.10; 57,541 (discussing the Agencies' interpretation of the word "as" to confer discretion to the Agencies). That suggestion is further reinforced by the absence of the words "evidence based" or "evidence-informed" in this subsection, as compared with parallel provisions § 300gg-13(a)(1) & (3), signaling that Congress authorized HRSA to consider policy-based factors beyond the scientific evidence in deciding whether to support a coverage mandate for particular preventive services.

Accordingly, § 300gg-13(a)(4) must be understood as a positive grant of authority for HRSA to develop the women's preventive-services guidelines and for the Agencies, as the administering agencies of the applicable statutes, to shape that development. *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and is subject to the agency's general supervision. *See* 47 Fed. Reg. 38,409-12 (Aug. 31, 1982). The text of § 300gg-13(a)(4) thus authorized HRSA to adopt guidelines for coverage that include an exemption for certain employers, and nothing in the ACA prevents HHS from supervising HRSA in the development of those guidelines. Indeed, since their first rulemaking on this subject in 2011, the Agencies

have consistently interpreted the broad delegation to HRSA in § 300gg-13(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage mandate. *See* 76 Fed. Reg. at 46,623.

In light of this statutory and regulatory backdrop, the Agencies' exercise of authority to expand the exemption is, at the very least, a reasonable construction of the statute entitled to deference. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

2. RFRA Justifies the Expanded Religious Exemption.

Even apart from § 300gg-13(a)(4), RFRA independently authorizes the religious exemption and the Settlement Agreement, if it does not require them outright. RFRA generally prohibits the government from "substantially burden[ing] a person's exercise of religion" unless the application of the burden to that person is "the least restrictive means" of furthering a "compelling governmental interest." 42 U.S.C. § 2000bb-1(b). Under *Hobby Lobby*, RFRA requires the government to eliminate the substantial burden imposed by the contraceptive-coverage mandate. The expanded religious exemption is a permissible—and in the case of some objecting employers, required—means of doing so.

In *Hobby Lobby*, the Supreme Court held that the contraceptive-coverage mandate, standing alone, "imposes a substantial burden" on objecting closely held, for-profit corporations with religious objections to providing contraceptive coverage. 134 S. Ct. at 2775-78. And the Court further held that application of the mandate to those objecting employers was not the least restrictive means of furthering any compelling governmental interest, because the accommodation would have satisfied the objecting employers' religious concerns in that case. *See id.* at 2780-83. But the Court did not decide whether the accommodation would satisfy

RFRA for all religious claimants, nor did it suggest that the accommodation is the only permissible way for the government to comply with RFRA and the ACA, even assuming the existence of a compelling governmental interest. *See id.* at 2782. Moreover, as the Agencies noted, other lawsuits and public comments have demonstrated that various entities object to complying with the accommodation. 83 Fed. Reg. at 57,546.

The Agencies reasonably decided to adopt the religious exemption to satisfy their RFRA obligation to eliminate the substantial burden imposed by the mandate. Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive-coverage mandate, per *Hobby Lobby*—RFRA does *not prescribe* the remedy by which the government must eliminate that burden. The Agencies previously chose to attempt to do so through the accommodation, but nothing in RFRA compelled that choice or prohibits the Agencies from now employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. Indeed, if the Agencies had simply adopted an exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because the Agencies should have created the accommodation instead. Neither RFRA nor the ACA compels a different result here based merely on path dependence.

The Agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given existing litigation over whether the accommodation violates RFRA. See 83 Fed. Reg. at 57,545; Priests for Life v. Health and Human Servs., 772 F. 3d 229 (D.C. Cir. 2014), vacated and remanded by Zubik v. Burwell, 136 S. Ct. 1557 (2016); Little Sisters of the Poor Home for the Aged v. Burwell, 794 F.3d 1151 (10th Cir. 2015), vacated and remanded

by Zubik v. Burwell, 136 S. Ct. 1557 (2016); Geneva Coll. v. Sec'y of Health & Human Servs., 778 F.3d 422 (3d Cir. 2015), 778 F.3d 422; Dordt Coll. v. Burwell, 801 F.3d 946 (8th Cir. 2015), vacated by Burwell v. Dordt Coll., 136 S. Ct. 1557 (2016); see also Ricci v. DeStefano, 557 U.S. 557, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate-impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban).

To be sure, if providing an exemption for an objecting religious employer would prevent the contraceptive-coverage mandate from achieving a compelling governmental interest as to that employer, then RFRA would not authorize that exemption. See Hobby Lobby, 134 S. Ct. at 2779-80. But the Agencies expressly found that application of the mandate to objecting entities—like Notre Dame—neither serves a compelling governmental interest nor is narrowly tailored to any such interest. That is so for multiple reasons, including: Congress did not mandate coverage of contraception at all; the preventive-services requirement was not made applicable to "grandfathered plans"; the previous religious exemption excused churches and their related auxiliaries, and also effectively exempted entities that participated in self-insured church plans; multiple federal, state, and local programs provide free or subsidized contraceptives for low-income women; entities bringing legal challenges to the mandate have been willing to provide coverage of some, though not all, contraceptives (as Notre Dame has done); and the Agencies have re-evaluated the administrative record supporting the contraceptive mandate and concluded that it is insufficient to establish a compelling government interest. See 83 Fed. Reg. at 57,546-48. Accordingly, the Agencies reasonably exercised their discretion in adopting the exemption as a valid means of complying with their obligation under RFRA to eliminate the

substantial burden imposed by the contraceptive-coverage mandate, whether or not the accommodation is a valid means of compliance. *See* 83 Fed. Reg. at 57,544-45.

This is especially true because the Agencies have concluded that the accommodation does violate RFRA for at least some employers and schools (like Notre Dame), by using plans that they themselves sponsor to provide contraceptive coverage that they object to on religious grounds, which they sincerely believe makes them complicit in providing such coverage. See 83 Fed. Reg. at 57,546. In light of those employers' and schools' sincere religious belief, forcing them to use the accommodation imposes a substantial burden under Hobby Lobby. See Sharpe Holdings, Inc. v. HHS, 801 F.3d 927, 939-43 (8th Cir. 2015), vacated and remanded sub nom. HHS v. CNS Int'l Ministries, No. 15-775, 2016 WL 2842448 (U.S. May 16, 2016). It thus was not just reasonable, but required, for the Agencies to provide an exemption to the contraceptive coverage mandate (rather than just the accommodation) to satisfy their RFRA obligations. See 83 Fed. Reg. at 57,546.

3. The Moral Exemption Rule Is Justified by Longstanding Precedent.

The moral exemption rule—which has not been invoked by Notre Dame and has no effect on Plaintiffs—is also well justified. It is designed to protect "sincerely held moral convictions" by exempting those with such convictions from facilitating the provision of contraceptive coverage. 83 Fed. Reg. at 57,593. The government may permissibly accommodate deeply held non-religious moral convictions and has furthered this important interest in a variety of contexts since the country's founding. *See Welsh v. United States*, 398 U.S. 333, 340 (1970) (individual qualified as a religious conscientious objector to the draft if he or she "deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to

that filled by . . . God' in traditionally religious persons") (plurality opinion); *United States v. Seeger*, 380 U.S. 163 (1965) (similar holding); *Doe v. Bolton*, 410 U.S. 179, 197-98 (1973); *see also* Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592, 57,601-02 (Nov. 15, 2018). Indeed, Congress has repeatedly legislated conscience protections in sensitive health contexts, including the provision of contraceptive services. *See* 83 Fed. Reg. 57,594 n.1 (collecting statutes). Moreover, many states, including Indiana, protect non-religious moral beliefs in healthcare. *See, e.g.*, 18 Pa. Stat. & Cons. Stat. Ann. § 3213 (West) (conscience clause permitting medical professionals and facilities to opt out of providing abortions); Cal. Health & Safety Code § 123420; Ind. Code §§ 16-34-1-3, 16-34-1-4; Md. Code Ann., Health – Gen. § 20-214. Plaintiffs' argument thus fails.

4. Plaintiffs' Additional Substantive APA Arguments Have No Merit.

Plaintiffs also claim that the Final Rules violate the APA because they are "inconsistent with the weight of the hundreds of thousands of comments that were submitted for each of the previous rules relating to the contraceptive coverage requirement, and the post-promulgation comments submitted following the Interim Final Rules." Am. Compl. ¶ 208. This allegation is based on a fundamental misunderstanding of administrative law. Under the APA, agencies do not count comments and then pick the version of the rule that has the most votes. "The substantial-evidence standard has never been taken to mean that an agency rulemaking is a democratic process by which the majority of commenters prevail by sheer weight of numbers." *Nat. Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 122 n.17 (D.C. Cir. 1987). Rather, an agency considers any comments that it receives on a proposed or interim final rule and determines, in the exercise of its discretion, what rule to adopt in view of those comments, statutory requirements, past regulations, and other relevant considerations. "The number and length of comments,

without more, is not germane" to this inquiry. *Id.* Here, the Agencies considered the comments they received, including by implementing a number of changes in response to the comments. *See, e.g.*, 83 Fed. Reg. at 57,537 (listing modifications to the religious exemption rule). That is all the APA requires.

D. The Court Should Dismiss Plaintiffs' Constitutional Claims.

1. The Final Rules and Settlement Agreement Do Not Violate the Establishment Clause (Count V).

Count V alleges that the Final Rules and Settlement Agreement violate the Establishment Clause because they are intended to and have the effect of advancing religious interests. Am. Compl. ¶ 216b. This claim has no merit. The Final Rules' protections for entities and individuals with sincerely held religious beliefs and moral convictions do not run afoul of the Establishment Clause. The Final Rules do not themselves promote or subsidize a religious belief or message, as demonstrated most clearly by the fact that their application is not limited to religious entities or persons. Instead, the Final Rules free entities and individuals with religious or moral objections to the provision of contraceptive coverage to act as they otherwise would in the absence of government-imposed regulations. If this Court reaches the merits of the Final Rules, it should hold that they represent a constitutional exercise of executive authority to alleviate unjustified substantial burdens on the exercise of moral convictions and religious beliefs.

When the government relieves such burdens, it does not violate the Establishment Clause; rather, "it follows the best of our traditions." *Zorach v. Clauson*, 343 U.S. 306, 314 (1952). The Supreme Court's cases "leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice." *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994). Rather, the Supreme Court "has long recognized that

the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause." *Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987) (quoting *Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136, 144-45 (1987)).¹⁰

The Supreme Court has repeatedly held that "there is room for play in the joints between' the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause." *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005) (quoting *Locke v. Davey*, 540 U.S. 712, 718 (2004)) (internal punctuation omitted). On that basis, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII's prohibition against religious discrimination in employment, *see Amos*, 483 U.S. at 335-39; a state property tax exemption for religious organizations, *see Walz*, 397 U.S. at 672-80; and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach*, 343 U.S. at 315.

The Seventh Circuit continues to apply the three-part test articulated in *Lemon v*. *Kurtzman*, 403 U.S. 602 (1971), to evaluate Establishment Clause challenges to government acts seeking to accommodate the practice of religious beliefs. *See Amos*, 483 U.S. at 335; *Sherman*

¹⁰ See also Lynch v. Donnelly, 465 U.S. 668, 673 (1984) ("Nor does the Constitution require complete separation of church and state; it affirmatively mandates accommodation, not merely tolerance, of all religions, and forbids hostility toward any."); Walz v. Tax Comm'n of City of New York, 397 U.S. 664, 676-77 (1970) ("Few concepts are more deeply embedded in the fabric of our national life . . . than for the government to exercise at the very least this kind of benevolent neutrality toward churches and religious exercise generally so long as none was favored over others and none suffered interference."); Lee v. Weisman, 505 U.S. 577, 627 (1992) (Souter, J., concurring) (stating that the Establishment Clause is not violated when the government accommodates religious beliefs "by relieving people from generally applicable rules that interfere with their religious callings").

ex rel. Sherman v. Koch, 623 F.3d 501, 507 (7th Cir. 2010). The Lemon test requires that government actions (1) have "a secular legislative purpose," (2) have a "principal or primary effect" that "neither advances nor inhibits religion," and (3) do not "foster an excessive government entanglement with religion." Lemon, 403 U.S. at 612-13 (citations and internal punctuation omitted). The Final Rules easily satisfy that test.

With respect to *Lemon*'s first prong, the Final Rules serve the legitimate secular purpose of alleviating significant governmental interference with the exercise of religion. *Amos*, 483 U.S. at 335; *see* 83 Fed. Reg. at 57,540 (purpose of the Rules is to "expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA").

As the Supreme Court has explained, the first prong of the *Lemon* test "does not mean that the law's purpose must be unrelated to religion—that would amount to a requirement 'that the government show a callous indifference to religious groups,' and the Establishment Clause has never been so interpreted." *Amos*, 483 U.S. at 335 (quoting *Zorach*, 343 U.S. at 314). "A statute may be motivated in part by a religious purpose and nonetheless satisfy the first criterion of *Lemon*." *Sherman*, 623 F.3d at 507 (citing *Wallace v. Jaffree*, 472 U.S. 38, 56 (1985)). "Thus, a secular purpose need not be the exclusive one; it is sufficient if the government had *a* secular purpose." *Id.* (citation and internal punctuation omitted). Furthermore, "the Supreme Court has recognized that the purpose prong of *Lemon* has rarely been determinative 'because [the] government does not generally act unconstitutionally, with the predominant purpose of advancing religion." *Id.* (quoting *McCreary Cty. v. ACLU of Ky.*, 545 U.S. 844, 863 (2005)).

Here, there is no indication in the Final Rules of any intent on the part of the Agencies to advance any particular faith or to promote religion in general. Instead, the Final Rules merely seek to alleviate certain substantial hardships faced by entities and individuals in the provision of health insurance. Indeed, the fact that the Final Rules also apply to entities and individuals with secular, non-religious moral beliefs regarding the provision of contraceptive coverage confirms that the Final Rules possess a secular purpose.

The Rules also satisfy the second prong of the *Lemon* test because their "principal or primary effect . . . neither advances nor inhibits religion." *Lemon*, 403 U.S. at 612. The Supreme Court has made clear that removing barriers to the exercise of religious freedom does not advance religion; to the contrary, "there is ample room for accommodation of religion under the Establishment Clause." *Amos*, 483 U.S. at 338. The Final Rules do not themselves promote or subsidize a religious belief or message; instead, they allow entities and individuals with objections to contraceptive coverage based on religious beliefs or moral convictions to practice those beliefs and convictions as they otherwise would in the absence of certain government-imposed regulations.

Finally, the Rules satisfy the third and final prong of *Lemon* because they do not "entangle the State in an unlawful fostering of religion." *Hobbie*, 480 U.S. at 145. In *Amos*, the Supreme Court upheld a statutory provision that exempted religious groups from Title VII's prohibition against religious discrimination, stating that "[i]t cannot be seriously contended that [the statute] impermissibly entangles church and state; the statute effectuates a more complete separation of the two." *Amos*, 483 U.S. at 339. The Final Rules operate in a similar manner: they reduce government interference with religious exercise. Far from entangling the

government in unlawful fostering of religion, the Final Rules in fact achieve a more complete separation of church and state.

In sum, the Final Rules have a secular purpose, their primary effect is neither to advance nor inhibit religion, and they do not foster excessive government entanglement with religion.

Accordingly, the Final Rules represent a permissible accommodation of religious beliefs and moral convictions consistent with the Establishment Clause.¹¹

2. The Final Rules and Settlement Agreement Do Not Violate the Due Process Clause (Count VI).

Plaintiffs' due process allegations comprise two distinct challenges, one substantive and one procedural. First, Plaintiffs allege that the Agencies have violated the substantive component of the Due Process Clause, by infringing on Plaintiffs' fundamental right to access contraceptives. Am. Compl. ¶ 220. Second, Plaintiffs maintain that the Agencies have violated procedural due process by depriving Plaintiffs of their liberty interest (in accessing contraceptives) without notice and an opportunity to be heard. *Id.* ¶ 221. Though distinct challenges, they both fail for the same reason: Plaintiffs do not have a constitutionally protected interest in receiving employer-subsidized contraceptives.

The substantive component of the Due Process Clause prohibits the government from taking certain actions regardless of the procedures it follows but (as is relevant here) only if the action would infringe on a fundamental right or liberty. *Daniels v. Williams*, 474 U.S. 327, 331 (1986); *Idris v. City of Chi.*, 552 F.3d 564, 566 (7th Cir. 2009). A fundamental right or liberty is one that is "deeply rooted in this Nation's history and tradition," and "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed."

¹¹ Plaintiffs' allegation that the Settlement Agreement violates the Establishment Clause, Am. Compl. ¶¶ 214, 216, fails for similar reasons.

Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997) (quotation marks omitted). Similarly, the procedural component of the Due Process Clause requires the government to satisfy certain procedural obligations with regard to an action but (as is relevant here) only if the government action jeopardizes a protected liberty interest. Santana v. Cook Cty. Bd. of Review, 679 F.3d 614, 621 (7th Cir. 2012) ("As a necessary component of a procedural due process claim, Santana must identify a protected property or liberty interest.").

Plaintiffs' due process allegations fail because the refusal to subsidize, or to require employers to subsidize, the use of contraceptives does not infringe on any protected liberty interest. The Supreme Court has recognized a fundamental right to privacy that encompasses certain decisions about contraceptive use. See, e.g., Griswold v. Connecticut, 381 U.S. 479 (1965); Eisenstadt v. Baird, 405 U.S. 438 (1972). But the Court has squarely rejected the argument that the refusal to fund the exercise of a liberty interest constitutes an infringement of that interest. For example, in Harris v. McRae, 448 U.S. 297 (1980), the Court considered the constitutionality of the Hyde Amendment, which restricted the use of federal funds for abortions. The Court concluded that "regardless of whether the freedom of a woman to choose to terminate her pregnancy for health reasons lies at the core or the periphery of the due process liberty recognized in Wade, it simply does not follow that a woman's freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices." Id. at 316. Put otherwise, the Court noted that "the Hyde Amendment . . . represents simply a refusal to subsidize certain protected conduct. A refusal to fund protected activity, without more, cannot be equated with the imposition of 'penalty' on that activity" in violation of the Constitution. Harris, 448 U.S. at 317 n.19; see also Maher v. Roe, 432 U.S. 464 (1977); Webster v. Reprod. Health Servs., 492 U.S. 490, 509 (1989).

The same logic applies here. The Final Rules and Settlement Agreement do not prohibit the use of any contraceptives or punish any women for their use. The Final Rules simply relieve entities with sincere religious or moral objections to all or some contraceptives from the obligation to subsidize or facilitate the subsidization of contraceptives to which they object. And the Settlement Agreement circumscribes the government's use of its enforcement discretion to achieve the same constitutionally permissible end, *i.e.*, the government has agreed not to enforce rules that require Notre Dame to subsidize or facilitate the subsidization of contraceptives to which it harbors a sincere religious objection. The Final Rules and Settlement Agreement, therefore, comport with the Due Process Clause.

3. The Final Rules and Settlement Agreement Are Consistent With Equal Protection Principles (Count VII).

Plaintiffs allege that the Final Rules and Settlement Agreement violate the equal protection principle of the Fifth Amendment in three ways: (1) "the expansive exemptions that they create impermissibly target women for adverse treatment," Am. Compl. ¶ 227; (2) they "endors[e] one set of religious beliefs to the exclusion of others," *id.* ¶ 228; and (3) "they discriminate against individuals who seek to exercise their fundamental right to make personal decisions regarding the use of contraception," *id.* ¶ 229. None of these arguments has merit. The Rules and Settlement Agreement do not discriminate on the basis of sex, facially or otherwise. Nor do they endorse any religion. *See supra* Part II.D.1. And they do not discriminate against those invoking their fundamental right to use contraceptives. Rather, they allow entities with sincere religious or moral objections to some or all contraceptives to decline to subsidize, or facilitate the subsidization of, those contraceptives to which they object, which is consistent with equal protection and due process principles given the absence of a fundamental

right to subsidized contraception. *See Harris*, 448 U.S. at 316 (finding no right to subsidized abortion).

When faced with a claim of discrimination on the basis of sex, courts assess (1) whether the classification is facially based upon sex and, if not, (2) whether there are other factors—such as the purpose of the law or the existence of a disparate impact—that demonstrate an invidious intent to discriminate on the basis of sex. *See Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979). With regard to "this second inquiry, impact provides an important starting point, but purposeful discrimination is the condition that offends the Constitution." *Id.* (citations omitted). Sex-based distinctions are subject to intermediate scrutiny, meaning that the distinction must be substantially related to an important governmental interest. *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142, 150 (1980). All other distinctions that do not target a protected class or burden a fundamental right are subject to rational-basis review. *Heller v. Doe*, 509 U.S. 312, 319–20 (1993). Under this standard, "a classification must be upheld ... if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *Id.* at 320 (citation omitted).

Plaintiffs contend that the "the expansive exemptions that the[] [Rules and Settlement Agreement] create impermissibly target women for adverse treatment," Am. Compl. ¶ 227. But neither the Rules nor the Settlement Agreement discriminates against women on the basis of sex, facially or otherwise. The Final Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing an exemption for those with religious and conscience objections. But the Final Rules and Guidelines do not require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8,458 n.3. Nor could they: the statutory provision requiring coverage for additional preventive services supported by HRSA pertains only to such services

for "women." 42 U.S.C. § 300gg-13(a)(4). Thus, the Final Rules do *not* treat men more favorably, and any sex-based distinctions flow from the statute requiring coverage of additional preventive services for women only, not from the Agencies "impermissibly targeting" women. Moreover, any distinctions in coverage among women are not premised on sex, but on the existence of a religious or moral objection by an individual's employer or school to facilitating the provision of contraceptives. Similarly, the Settlement Agreement does not draw any sex-based distinctions. Rather, it provides to Notre Dame, via an exercise of enforcement discretion memorialized in a contract, the same basic protection from government enforcement provided to all religious objectors by the rule-based exemptions. As with the Final Rules, any sex-based distinctions flow from the statute requiring preventive services for women only, not from the Agencies "impermissibly targeting" women.

Because the Final Rules and Settlement Agreement do not create sex-based distinctions, they are subject to rational basis review. And they satisfy "the low bar of rational basis review," *Sweeney v. Pence*, 767 F.3d 654, 668 (7th Cir. 2014), because they are rationally related to legitimate government interests, *Lyng v. Int'l Union of United Auto. Workers*, 485 U.S. 360, 370 (1988). The religious exemption rule accommodates religion by "expand[ing] exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage." 83 Fed. Reg. at 57,540. The Settlement Agreement does the same. And the accommodation of religious beliefs is an important government interest, as the Supreme Court recognized in *Cutter*, 544 U.S. at 724-25. Indeed, for the same reasons, the rule and Settlement Agreement would satisfy intermediate scrutiny.

The Moral Exemption Rule also has a rational basis (and also satisfies intermediate scrutiny). It is designed to protect sincerely-held "moral convictions" by exempting those with such convictions from facilitating the provision of contraceptive services. 83 Fed. Reg. at 57,596. The government may permissibly accommodate deeply held moral, but not necessarily religious, convictions and has furthered this important interest in a variety of contexts since the founding. *See Welsh*, 398 U.S. 333; *Seeger*, 380 U.S. 163; *Bolton*, 410 U.S. 179; 82 Fed. Reg. at 47,838 n.1.

Plaintiffs also allege that the Final Rules and Settlement Agreement "discriminate against individuals who seek to exercise their fundamental right to make personal decisions regarding the use of contraception," Am. Compl. ¶ 229, and that the government cannot satisfy the exacting scrutiny that attaches to such a classification, id. ¶ 230. This argument is flawed. "[E]qual protection analysis requires strict scrutiny of a [governmental] classification only when the classification impermissibly interferes with the exercise of a fundamental right." Mass. Bd. of Ret. v. Murgia, 427 U.S. 307, 312 (1976). And while, as noted earlier, the Supreme Court has recognized a fundamental right to privacy that encompasses decisions about contraceptive use, see, e.g., Griswold, 381 U.S. 479, it has also clearly held that a fundamental right is not infringed by a mere lack of subsidization, see Harris, 448 U.S. at 316. The Final Rules and Settlement Agreement address the subsidization of contraceptives and thus do not infringe on any fundamental right. The Final Rules and Settlement Agreement distinguish between those who attend school at, or are employed by, a school or employer that object to some or all contraceptives, and those who attend school or work at a non-objecting school or employer. As discussed earlier, this distinction is subject to rational basis review, a low bar that it easily

passes. Plaintiffs remain free to use contraceptives, as well as to seek out contraceptive coverage from other sources. Plaintiffs' equal protection allegations fail.

CONCLUSION

For the foregoing reasons, the Federal Defendants respectfully request that the Court dismiss this action for lack of subject matter jurisdiction and failure to state a claim on which relief can be granted.¹²

Dated: February 12, 2019 Respectfully submitted,

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¹² Plaintiffs are not entitled to any relief, as explained above. But, should the Court ultimately decide otherwise, Federal Defendants request the right to submit additional briefing on the appropriate remedy. Relevant to that discussion will be the scope of relief necessary to provide complete relief to Plaintiffs, as well as the severability provision of the Final Rules, 83 Fed. Reg. at 57,589 (religious exemption rule); 83 Fed. Reg. at 57,624 (moral exemption rule).

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